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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/101,672	10/23/98	BARTLETT R	02481.1603

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1623	9

DATE MAILED: 12/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/101,672	Applicant(s) BARTLETT et al.
	Examiner WHITE	Group Art Unit 1623

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *12-29* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *12-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-19, 22-25, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The dependence of claims 13-19 and 29 from claim 1 is improper and renders the claims indefinite since claim 1 has been canceled. See preliminary amendment A filed July 15, 1998. It appears that these claims were intended to be dependent from claim 12.

Claims 22-25 and 28 refer back to claims 12, 13, 15 and 18 as methods which is improper since claims 12, 13 and 15 are drawn to compositions.

3. Claims 18 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. .

Claims 18 and 19 are objected to as being incomplete for omitting essential cooperative relationships of elements (the first and second components together in the same composition), such omission amounting to a gap between the necessary connections. The claimed limitation in claims 18 and 19 of separating the first and second components in the composition of claim 12 (assuming that claims 18 and 19 were intended to be dependent from claim 12) is improper and do not further limit the subject matter of claim 12 since the first and second components in the instant claims are essential components of the composition.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartlett et al (US Patent No. 4,965,276).

Bartlett et al disclose a pharmaceutical composition for use in the treatment of autoimmune diseases containing as an active ingredient at least one compound of the formulae 1 or 2 (see abstract). Compounds 1 and 2 of the Bartlett et al patent are similar to the compound structure and names of the first and second components disclosed in the instant claims. See column 6, 2nd paragraph of the Bartlett et al patent wherein compounds 1 and 2 may be administered orally or rectally which would allow the claims to have similar or different administration forms as set forth in instant claims 18 and 19. The Bartlett et al patent anticipates the claim limitations disclosed in instant claims 18 and 19 whereby the first and second components are indicated as being separate. By disclosing the phrase "at least one compound of formulae 1 or 2" in the abstract of the Bartlett et al patent, compounds of formulaw 1 and 2 may be present together in the pharmaceutical composition or each component may be present in separate pharmaceutical compositions.

6. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Bartlett et al (WO 91/17748).

Bartlett et al's WO patent discloses isoxazole-4-carboxamide derivatives and hydroxyalkylidene-cyanoacetamide derivatives which include the specifically recited compounds of instant claim 27 (see compounds 1 and 2 under Beispiel 4 (Example 4) page 21, lines 2 and 3 and lines 14 and 15 of the WO patent) which are suitable for the treatment of cancer diseases (see abstract) which anticipates the subject matter of claim 27 of the instant application.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartlett et al (US Patent No. 4,965,276).

Applicants claim a solid composition comprising a first component comprising 5-methyl-4'-trifluoromethyl-4-isoxazolecarboxanilide; a second component comprising a compound of formula I as disclosed in claim 1 (named N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonic acid amide); and a third component comprising a pharmaceutically tolerated excipient; wherein the first component has a concentration from about 2 to about 20 mg and the second component has a concentration from about 0.3% to about 50% of the first component.

Bartlett et al disclose a pharmaceutical composition for use in the treatment of autoimmune diseases containing as an active ingredient at least one compound of the formulae 1 or 2 (see abstract). Compounds 1 and 2 of the Bartlett et al patent are similar to the compound structure and names of the first and second components disclosed in the instant claims. See column 6, 2nd paragraph of the Bartlett et al patent wherein compounds 1 and 2 may be administered orally or rectally as set forth in instant claim 17. The Bartlett et al patent meets the claim limitations disclosed in instant claims 18 and 19 whereby the components are viewed as being separate components by disclosing the phrase "at least one compound of formulae 1 or 2" in the abstract. The phrase indicates that the compounds may be present together in the pharmaceutical composition or each compound may be present in separate pharmaceutical

compositions. The Bartlett et al patent further discloses administration of the pharmaceutical products in dosage units, each unit containing as the active ingredients a defined dose of compound 1 and/or 2, the dose ranging from 10 to 200 mg (see column 6, 3rd paragraph). The use of the pharmaceutical composition of the Bartlett et al patent to treat autoimmune diseases is within the scope of the method of claims 20-26 which set forth a method of treating an immunological disease comprising administering to a patient the instantly claimed composition. See column 1, line 65 to column 2, line 6 of the Bartlett et al patent wherein it is disclose that autoimmune disease includes systemic lupus erythematosus which is not specific to any organ. Bartlett et al disclose that the external manifestations of systemic lupus erythematosus are lesions on the facial skin. Bartlett et al disclose that in most cases, other areas of the skin and the mucosa are affected. Bartlett et al further disclose that nephritis, endocarditis, hemolytic anemia, leukopenia and involvement of the central nervous system are also observed. The instant claims differ from the Bartlett et al patent by reciting in claims 12-16 that the second component (the compound of formula I (or the compound named N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonic acid amide)) has a concentration from about 0.3% to about 50% of the first component (the compound named 5-methyl-4'-trifluoromethyl-4-isoxazolecarboxanilide) which is not specifically disclosed in the Bartlett et al patent. However, this limitation appears to be obtainable by the Bartlett et al patent in view of the description for administering compounds 1 and/or 2 in dosage units as described in the 3rd paragraph of column 6 of the Bartlett et al patent. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicants invention having the Bartlett et al patent before him and the information disclosed therein wherein compounds 1 and/or 2 may be administered in dosage units ranging from 10 to 200 mg to meet the instantly claimed limitation of the second component having a concentration from 0.3% to 50% of the first component in view of their closely related structures and the resulting expectation of similar immunological properties.

9. All the pending claims (12-29) are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

White

December 3, 1999

Gary L. Kunz

GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200